DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 31, 2015

Unimicro Medical Systems (ShenZhen) Co., Ltd.
Weizhong Chen
Vice General Manager
2/f, Bldg 31, The 3rd Industrial Area, Mashantou,
Gongming Street, Guangming New District
ShenZhen City, Guangdong 518106
China

Re: K150068
Trade/Device Name: Unimicro Veress Needle
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF, FHO
Dated: June 17, 2015
Received: June 23, 2015

Dear Weizhong Chen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150068

Device Name
Unimicro Veress Needle, models : MND 11200, MND 11500

Indications for Use *(Describe)*
The Unimicro Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Unimicro Medical Systems (ShenZhen) Co., Ltd.

510(K) SUMMARY

This 510(k) summary is being submitted in accordance with 21 CFR §807.92.

Type of submission: Traditional

The assigned 510(K) number is: K150068

Date of Preparation: JULY 1, 2015

1. Submitter information:

Manufacturer Name: Unimicro Medical Systems (ShenZhen) Co.,Ltd.

Address: 2/F, Bldg 31, The 3rd Industrial Area, Mashantou, Gongming Street, Guangming New District, ShenZhen City,Guangdong Province, China

Tel: 0086-755-27111581

Fax: 0086-755-27111580

Establishment Registration Number: 3010806467

2. Contact person:

Mr. Weizhong Chen (Vice General Manager)

E-mail: info@unimicromed.com

3. Identification of the Device :

Trade Name: Unimicro Veress Needle

Common Name: Veress Needle

Model: MND 11200, MND 11500

Classification Name	Product Code	Regulation Number	Regulatory Class	Review Panel
Insufflator, Laparoscopic	HIF	21CFR 884.1730	II	Obstetrics/Gynecology
Pneumoperitoneum Needle	FHO	21CFR 876.1500	II	Gastroenterology/ Urology

4. Identification of the Predicative Device

Table 1: Predicative Device Information

Device Name	Common Name	Manufacturer	Classification and Product Code	Classification regulation	510(k) number
Unimax Veress Needle	Veress Needle	Unimax Medical Systems Inc.	Class II, HIF	21CFR 884.1730	K111441
			Class II, FHO	21CFR 876.1500	

5. Indications for Use

The Unimicro Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

6. Device Description

The Unimicro Veress Needle is a sterile and single-use product. It incorporates a spring-loaded blunt stylet mechanism. It is used to establish peritoneum prior to trocar and cannula insertion in laparoscopic procedures. The Unimicro Veress Needle, available in 120 mm and 150 mm lengths, has applications in gynecological laparoscopy and other laparoscopic procedures.

7. Non-clinical Testing

A series of in vitro and in vivo preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the Unimicro Veress Needle. The tests listed below were conducted in accordance with ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, ISO 10993-12:2012 and ISO 11135-1:2007.

- Cytotoxicity Test
- Skin irritation Test
- Skin Sensitization Test（the Guinea Pig maximization test)

- EO Sterilization Validation
- Ethylene Oxide Sterilization Residuals Test

The tests listed below have demonstrated that the subject device performs as well as the predicate device.

- Tip Pull Test
- Switch Operation
- Spring Obturator Operation
- Needle Puncture Force Test

In each of the above tests, the Unimicro Veress Needle met the requirements ofthe pre-defined acceptance criteria.

The results of the non-clinical testing demonstrate that the Unimicro Veress Needle is as safe and effective as the predicate device.

8. Substantial Equivalence Determination

The Unimicro Veress Needle submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Unimax Veress Needle which is the subject of K111441. There are no differences between the two devices that raise any new issues of safety or effectiveness.

The comparison to predicate device as below Table 2.

Table 2 : Comparison to Predicate Device

Item	Proposed Device	Predicate Device
Trade Name	Unimicro Veress Needle	Unimax Veress Needle
510(K) Submitter	Unimicro Medical Systems (ShenZhen) Co.,Ltd.	Unimax Medical Systems Inc.
510(K) Number	-	K111441
Classification regulation	21CFR 884.1730 21 CFR 876.1500	21CFR 884.1730 21 CFR 876.1500
Classification and Code	Class Ⅱ, HIF,FHO	Class Ⅱ, HIF,FHO
Common name	Veress Needle	Veress Needle
Intended Use	The Unimicro Veress Needle	The Unimax Veress Needle is

	is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.	intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.
Consisted Instruments	Veress Needle Obturator	Veress Needle Obturator
Models	MND 11200,MND 11500	xVN Series
Length	120mm,150mm	120mm,150mm
Sterilization	EO Sterilized	EO Sterilized
Disposable	Yes	Yes
Principles of operation	Connect the device to the insufflators with insufflation tubing, insufflating with carbon dioxide to establish pneumoperitoneum	Connect the device to the insufflators with insufflation tubing, insufflating with carbon dioxide to establish pneumoperitoneum
Safety standards	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-7:2008 ISO 10993-10:2010 ISO 10993-12:2012 ISO 11135-1:2007	ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-12 ISO 11135-1
Performance standards	Not Applicable	Not Applicable
Compared performance testing	· Tip Pull Test · Switch Operation · Spring Obturator Operation	· Tip Pull Test · Switch Operation · Spring Obturator Operation

	· Needle Puncture Force Test	· Needle Puncture Force Test

9. Conclusion

Based upon the non-clinical performance and safety tests, it can be concluded that the Unimicro Veress Needle is as safe and effective as the predicate device. Therefore, Unimicro Veress Needle is substantially equivalent to the Unimax Veress Needle.